Proposed Re-evaluation Decision PRVD2017-11

Fluroxypyr (present as ester) and Its Associated End-use Products

Consultation Document

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of the herbicide fluroxypyr (present as ester), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing fluroxypyr for sale and use in Canada.

An evaluation of available scientific information found that products containing fluroxypyr do not present unacceptable risks to human health or the environment when used according to the revised label directions. As a condition of the continued registration of fluroxypyr uses, new risk-reduction measures are proposed to be included on the labels of all products.

This proposal affects all end-use products containing fluroxypyr registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision (PRVD) is a consultation document[1] that summarizes the science evaluation for fluroxypyr and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The 'Overview' describes the regulatory process and key points of the evaluation, while the 'Science Evaluation' provides additional technical information on the assessment of fluroxypyr.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (please see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What Is Fluroxypyr (present as ester)?

Fluroxypyr is a post-emergent herbicide that offers control of hard-to-kill annual broadleaved weeds in small grain cereals, rangeland, permanent pasture, industrial and other non-cropland areas. It is applied with both ground and aerial equipment and works by disrupting plant cell growth in the newly forming stems and leaves of susceptible plants.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

Health Considerations

Can Approved Uses of Fluroxypyr Affect Human Health?

Fluroxypyr is unlikely to affect your health when used according to the revised label directions.

When assessing health risks, two key factors are considered by the PMRA: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Potential exposure to fluroxypyr may occur through diet (consuming food and water), and/or when handling the product or entering a treated site as a worker.

Dietary exposure to fluoxypyr through consumption of food commodities and drinking water is not of concern for Canadians when fluroxypyr is used according to label directions. Occupational risks, such as mixing, loading, and applying pest control products containing fluroxypyr and/or entering a treated site, are also not of concern when fluroxypyr is used according to label directions. These directions include protective measure statements such as the minimum required personal protective equipment for workers. As well, taking into consideration the use pattern of fluroxypyr, residential exposure is not expected.

Additional label statements are proposed to be added to the product labels in order to update all labels to the current standard (see Measure to Minimize Risk).

Environmental Considerations

What Happens When Fluroxypyr Is Introduced Into the Environment?

When used according to the label directions, fluroxypyr is not expected to pose risks of concern to the environment.

Fluroxypyr (fluroxpyr-methylheptyl ester) enters the environment when applied as a herbicide to agricultural fields and non-crop areas for the control of weeds. Fluroxypyr does not mix well with water and in small amounts may evaporate from moist soil and water surfaces and enter the atmosphere. Fluroxypyr breaks down quickly and is not expected to build-up in soil and water. Fluroxypyr is not expected to be mobile in soil and has a very low potential to move through the soil and reach groundwater.

The breakdown products of fluroxypyr (fluroxypyr acid, dichloropyridinol and its derivatives, and methoxypyridine) all break down more slowly in the environment than fluroxypyr, are expected to be mobile in soil and have some potential to move through the soil and reach groundwater. Fluroxypyr is not expected to accumulate in the tissues of organisms.

Fluroxypyr does not present a risk of concern to wild mammals, birds, bees, invertebrates, or freshwater and marine invertebrates. However, exposure to fluroxypyr can affect non-target plants on land, freshwater algae, freshwater fish, amphibians, and marine minnows if they are exposed to high enough levels. To protect non target organisms on land and in water from spray drift, updated buffer zones are proposed. To protect aquatic organisms from the potential effects of run-off, updated label statements informing users how to reduce run-off are proposed along with revised precautionary label statements to inform users of the toxicity of fluroxypyr.

Value Considerations

What is the Value of Fluroxypyr?

Fluroxypyr is an important herbicide for Western Canadian. It offers control of hard-to-kill annual broadleaved weeds, and it has value with respect to the weed management program for cereal production (wheat, barley, and oats). It also has significant value as an important weed management tool for the seed production of forage grasses and the management of pasture, rangeland, and industrial non-crop areas.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of fluroxypyr, the PMRA is proposing the following risk-reduction measures related to human health and the environment for product labels:

- Buffer zones and label statements to protect non-target terrestrial plants and aquatic organisms

In addition, changes in the following areas are proposed to update all labels with current PMRA standard practices:

- Restricted-entry Interval (REI) of 12 hours
- Precautionary label statements to minimize bystander exposure from spray drift
- Environmental hazard label statements
- Storage label statements

What Additional Scientific Information Is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on fluroxypyr, the PMRA will consider any comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision, and the PMRA's response to these comments.

[2] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Fluroxypyr is a systemic herbicide that is registered for the selective control of post-emergent broadleaf weeds. Currently registered products containing fluroxypyr are listed in Appendix I.

2.0 Use Description of Fluroxypyr

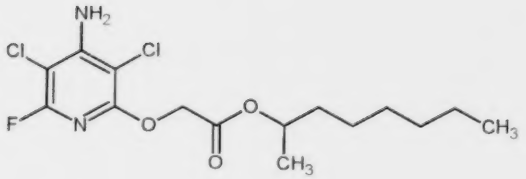
Fluroxypyr offers control of broadleaved weeds in small grain cereal crops, winter wheat, foxtail millet, forage grasses grown for seed, canary seed, pasture, rangeland, industrial and other non-cropland areas. Fluroxypyr products are formulated as emulsifiable concentrate, suspension, or wettable granules; however, in many cases, fluroxypyr is co-formulated, or used in tank mixtures, with other herbicides to broaden the weed control spectrum. Fluroxypyr is applied once or twice per year depending on the end-use product and specified use profile, using ground and/or aerial application equipment. The rate of application ranges from 0.048 to 0.280 kg a.e./ha depending upon the use sites as well as the weed control spectrum.

3.0 The Technical Grade Active Ingredient and Its Properties

The ester form of fluroxypyr (fluroxypyr-meptyl; fluroxypyr-methylheptyl ester; fluroxypyr 1-methylheptyl ester) is employed as the technical grade active ingredient. The ester form is hydrolysed to fluroxypyr acid (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyacetic acid), which is the herbicidal active form.

3.1 Identity of the Technical Grade Active Ingredient

Common name	Fluroxypyr-meptyl
Function	Herbicide
Chemical family	Pyridine carboxylic acid
Chemical name	
1 **International Union of Pure and Applied Chemistry (IUPAC)**	(*RS*)-1-methylheptyl 4-amino-3,5-dichloro-6-fluro-2-pyridyloxyacetate
2 **Chemical Abstracts Service (CAS)**	1-methylheptyl 2-[(4-amino-3,5-dichloro-6-fluoro-2-pyridinyl)oxy]acetate
CAS Registry Number	81406-37-3

Structural Formula			
Molecular Weight	367.25		
Registration Number and Purity of the Technical Grade Active Ingredient	24814 68%	30335 68%	30507 68%

3.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result
Vapour Pressure (mPa at 20°C)	1.349×10^{-3}
Ultraviolet / visible spectrum	No significant absorption between $\lambda > 290$ nm
Solubility in Water at 20-25°C	0.09 mg/L
Dissociation Constant	$pK_a = 6.60$
n-Octanol–water partition coefficient (K_{ow})	pH log K_{ow} 5 4.53 7 5.04

4.0 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical, and they also identify dose levels at which no adverse effects are observed (that is, the No Observed Adverse Effect Level – NOAEL). The health effects noted in animals occur at doses more than 100 times higher (and often much greater) than levels to which humans are normally exposed when pesticide products are used according to label directions.

When assessing health risks, the PMRA considers two key factors: the levels at which no adverse health effects occur, and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population, for example, children and nursing mothers. As such, sex and gender are taken into account in the risk assessment. Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Based on the registered use pattern, exposure to fluroxypyr may occur through consuming food and drinking water, working as a mixer/loader/applicator, or by entering treated sites.

4.1 Toxicological Summary

The toxicology database submitted for fluroxypyr is adequate to define the majority of toxic effects that may result from exposure. There was no evidence of oncogenicity in rats or mice after long-term dosing. Fluroxypyr was not genotoxic. There was no evidence of increased susceptibility of the young in reproduction or rat developmental toxicity studies. There was increased susceptibility of the foetus in the rabbit developmental study, however, the effect was not considered serious in nature. Fluroxypyr did not appear to be neurotoxic. In short-term and chronic studies in laboratory animals, the primary target was the kidney. The risk assessment protects against the toxic effects noted above by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. For more details, please refer to PRD2012-18

No additional toxicology data is required for re-evaluation. Appendix II summarizes the fluroxypyr toxicology endpoints and reference values used in human health risk assessments by the PMRA.

4.2 *Pest Control Products Act* Hazard Characterization

The *Pest Control Products Act* factor was previously assessed and reduced to 1-fold for fluroxypyr. For more details, please refer to PRD2012-18.

4.3 Occupational Exposure

Occupational risk is estimated by comparing potential exposure with the most relevant endpoint from toxicology studies. A margin of exposure (MOE) is calculated for a specified use pattern, and this value is compared to a target MOE, which incorporates uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects but that mitigation measures to reduce risk will be required.

Workers can be exposed to fluroxypyr through mixing, loading, and /or through applying the product using several ground application methods, as well as with aerial sprayers. Workers can also be exposed when entering a treated site to conduct activities such as scouting, mechanical weeding, irrigation, and mowing.

4.3.1 Mixer/Loader/Applicator Exposure and Risk

Based on the fluroxypyr use pattern (ground and aerial application), mixer/loader/applicator exposure is expected to be mainly via dermal and inhalation routes.

Exposure for workers mixing/loading and applying fluroxypyr based on the registered use patterns was estimated with unit exposure values from the Pesticide Handlers Exposure Database, version 1.1, and standard assumptions including the assumption that workers were wearing the personal protective equipment listed on the label (coveralls over a single layer of

clothing plus chemical-resistant gloves; goggles or face shield during mixing, loading, repair and clean-up or when handling the concentrate; no gloves for applicators using closed cab groundboom and aerial equipment).

The calculated short- and intermediate-term dermal MOEs (>12,900) and inhalation MOEs (>27,100) were well above the target MOE of 100 for all scenarios. On this basis, the risk for workers mixing, loading and applying the herbicide using either ground or aerial application methods is not of concern when wearing the label-indicated personal protective equipment.

No additional mitigation measures are proposed.

4.3.2 Postapplication Exposure and Risk

Fluroxypyr is regarded as non-volatile with a vapour pressure of 1.012×10^{-8} mm Hg at 20°C. This meets the North American Free Trade Agreement (NAFTA) criterion for a low-volatility inhalation waiver, as it has a vapour pressure of less than 7.5×10^{-4} mm Hg (NAFTA, 1999). Thus, inhalation exposure is deemed minimal and is not of concern for postapplication activities. In view of that, dermal exposure is considered to be the primary route of exposure for workers entering treated fields to conduct postapplication activities.

The dermal exposure estimates for postapplication workers were assessed assuming a dislodgeable foliar residue value of 25% based on a single application using the maximum aerial application rate and maximum applicable transfer coefficient associated with cereal crops. Using standard assumptions, the calculated dermal MOE (>22,000) was well above the target MOE of 100 on the day of application.

On this basis, the postapplication risk for workers entering treated fields is not of concern. The current restricted-entry interval of 12 hours is sufficient to protect workers from postapplication occupational health risks.

A label amendment is proposed to specify a restricted entry interval of 12 hours for all product labels that do not currently specify a REI. The proposed label statements are listed in Appendix III.

4.4 Non-occupational Exposure

4.4.1 Residential Exposure and Risk

There are no registered residential uses of fluroxypyr nor is it expected that the commercial products would be applied in residential areas. Standardized statements are proposed to specify that (1) application is limited to agricultural crops and industrial/commercial non-food crop sites and that (2) application should be limited to when the spray is unlikely to drift into areas of human habitation or activity such as houses, cottages, schools and recreational areas. The proposed label statements are listed in Appendix III.

4.4.2 Dietary Exposure and Risk

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in meat and milk may be ingested with the daily diet (food and drinking water). These dietary assessments are age-specific and incorporate different eating habits of the population at various stages of life (infants, children, adolescents, adults, and seniors). For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults.

The residue definition of fluroxypyr in Canada under the *Pest Control Products Act* in plants and animals is the parent compound, fluroxypyr-methylheptyl ester and fluroxypyr acid. The residue definition for dietary exposure and risk assessment of fluroxypyr in water is fluroxypyr-methylheptyl ester, fluroxypyr acid, and methoxypyridine.

An acute reference dose for fluroxypyr was not determined since a toxicological endpoint of concern attributable to a single dose was not identified. As well, a cancer potency factor was not assigned as there was no cancer endpoint. Therefore, acute and cancer dietary exposure assessments were not required.

The chronic dietary exposure (from food and drinking water) was calculated using the average consumption of different foods and water and the estimated residue values of fluroxypyr on and/or in those foods and water. When the calculated intake of residues from all food sources (including water) is less than the ADI, then chronic dietary exposure is not of concern. The ADI for fluroxypyr was determined to be 1.0 mg/kg bw/day (see Appendix II).

The chronic dietary exposure assessment was conducted using Canadian MRL level residues and American tolerances for all food commodities with default food processing factors, and the assumption that 100% of the crop was treated. For water, the estimated concentrations in potential drinking water sources (groundwater and surface water) were generated using modeling and conservative assumptions with respect to environmental fate, application rate and timing, geographic scenario, and weather data. Considering both ground water and surface water estimates, the highest concentration value for the combined residues of fluroxypyr and its transformation products was used in the chronic dietary exposure assessment.

The basic chronic dietary exposure to fluroxypyr from both food and drinking water (aggregate) represented less than 1.0% of the ADI for the general population, and 2.1% of the ADI for the most exposed population subgroup (children, 1-2 years old). On this basis, dietary exposure to fluroxypyr is therefore not of concern for all populations.

4.5 Aggregate Exposure and Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal, and inhalation).

For fluroxypyr, aggregate exposure is limited to food and drinking water only. As noted above, aggregate dietary exposure from food and drinking water is not of concern, for all population subgroups (see Section 4.4 for details).

4.6 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. For the current re-evaluation, the PMRA did not identify information indicating that fluroxypyr shares a common mechanism of toxicity with other pest control products. Therefore, there is no requirement for a cumulative assessment at this time.

5.0 Environment

Fluroxypyr enters the environment when applied as an herbicide to agricultural fields and non-crop areas for the control of weeds. Non-target terrestrial and aquatic habitats may be exposed to the chemical as a result of spray drift or runoff

The risk assessment conducted previously (2012) has been determined to meet the current standards in most areas. However, based on the new information received on marine fish (Sheepshead Minnows), the PMRA updated the aquatic (marine) risk assessment. A summary of this updated aquatic risk assessment, as well as the existing assessment is presented below. For more details on the PMRA's environmental assessment, please refer to PRD2012-18..

5.1 Environmental Fate

The technical grade active ingredient of fluroxypyr is composed of the ester form of fluroxypyr (fluroxypyr-methylheptyl ester). Fluroxypyr-methylheptyl ester is sparingly soluble and slightly volatile from water surfaces and moist soils. Fluroxypyr-methylheptyl ester is non-persistent as it transforms to its acid equivalent in both aerobic soils and water/sediment systems. Fluroxypyr-methylheptyl ester is classified as immobile in soil and has very low potential to leach to groundwater. Although the octanol-water partition coefficient for fluroxypyr-methylheptyl ester indicated a potential to bioaccumulate, bioaccumulation in aquatic biota is not expected based on a fish bioaccumulation study.

Fluroxypyr acid is very soluble in water and is non-volatile from water surfaces and moist soils. In aerobic soils, fluroxypyr acid is non-persistent to moderately persistent. In water, it is slightly persistent. Major biotransformation products of fluroxypyr acid include methoxypyridine and dichloropyridinol in soil, and dichloropyridinone and chloropyridinol in aquatic systems. Fluroxypyr acid is highly mobile in soil but, from soil dissipation studies, has low to moderate potential to leach to groundwater.

In aerobic soils, both dichloropyridinol and methoxypyridine biotransformed to non-extractable residues and carbon dioxide. Dichloropyridinol is slightly to moderately persistent and methoxypyridine is persistent. In water, both dichloropyridinone and chloropyridinol are slightly persistent, biotransforming to carbon dioxide. Dichloropyridinol and its derivatives, as well as methoxypyridine have moderate to high mobility in soil but, in field dissipation studies, they too showed low potential to leach to groundwater.

5.2 Environmental Exposure and Risk Assessment

5.2.1 Terrestrial Organisms

Based on the existing risk assessment, earthworms, pollinators, beneficial arthropods, birds, and small wild mammals are not expected to be at risk from the application of fluroxypyr. To mitigate potential risk identified for non-target vascular plants, no-spray terrestrial buffer zones are proposed (Appendix III).

5.2.2 Aquatic Organisms

Based on the existing risk assessment, freshwater invertebrates and marine algae are not expected to be at risk from the application of fluroxypyr; however, a potential risk of concern was identified for freshwater fish, amphibians, and freshwater algae.

Based on the new information on marine fish, the previously used marine endpoint (EC_{50} = 0.208 mg a.i./L, algae, *Skeletonema costatum*) for risk assessment has been revised. A new risk assessment was conducted with the updated endpoint for marine organisms (LC_{50} >0.0866 mg a.i./L, minnow, *Cyprinodon variegatus*), based on screening level EECs from the direct application of fluroxypyr-methylheptyl ester. Using the sheepshead minnow endpoint, the level of concern was slightly exceeded (RQ<2.9).

To mitigate potential risk identified for freshwater and marine organisms, updated no-spray aquatic buffer zones are proposed, as well as standard environmental label statements for run-off (Appendix III).

6.0 Value

Fluroxypyr offers control of hard-to-kill annual broadleaved weeds such as cleavers, kochia and chickweed, which are becoming more abundant in Western Canada. Accordingly, it has value in weed management for cereal production (wheat, barley, and oats) as (I) many different herbicides used in cereal crops are often co-formulated, or in tank mixture, with fluroxypyr; (II) when co-formulated or in tank mixtures with other herbicides, fluroxypyr controls some troublesome perennial broadleaved weeds such as Canada thistle and perennial sow thistle; and (III) fluroxypyr provides an approach to tackle some herbicide resistant weed species such as the ALS (Group 2 herbicide) resistant kochia. It also has significant value as an important weed management tool for the seed production of forage grasses and for the management of pasture, rangeland, and industrial non-crop areas.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

In PRD2012-18, Fluroxypyr-methylheptyl ester, fluroxypyr acid, and their transformation products were previously assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, and were found not to meet the Track 1 criteria.

7.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of fluroxypyr, contaminants in the technical were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3]. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03, DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade fluroxypyr has been shown to contain polychlorinated dibenzo-p-dioxins and dibenzofurans substituted in at least the 2,3,7,8 positions: contaminants which have been identified in the federal government's Toxic Substances Management Policy (TSMP, 1995) as Track 1 substances.

- The PMRA is managing the presence of these contaminants in accordance with the Agency's strategy to prevent or minimize releases, with the ultimate goal of virtual elimination, as described in DIR99-03.

- The use of formulants in registered pest control products is assessed on an ongoing basis through the PMRA formulant initiatives and Regulatory Directive DIR2006-02.

8.0 Incident Reports

Since 26 April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame.

As of 15 June 2017, twelve human incidents involving fifteen people, one domestic animal incident, and eight environment incidents have been received by the PMRA. While the majority of incidents also involved multiple active ingredients, which confounds any fluroxypyr-specific

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[3] *Canada Gazette*, Part II, Volume 139, Number 24, pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, pages 1611-1613, *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

conclusions regarding adverse effects, no risks of concern were identified in the health or environmental incident report data that warranted addition mitigation.

The human incidents involved accidental exposure during the mixing, loading or application of the product, or during the maintenance of sprayer equipment. Ten incidents reported minor symptoms, such as eye or respiratory irritation. One incident was reported as a major incident, but the PMRA determined that the severity of this incident as being moderate; symptoms included tachycardia and lethargy. The major incidents that had occurred in the United States were also received and evaluated as unlikely to have been associated to the reported exposures. In one of these cases, the individual experienced liver failure after accidentally getting some of the product on his skin, and in the other, a woman experienced an unidentified respiratory condition that required regular hospital admittance after being regularly exposed to contaminated clothing.

All environmental incidents were minor in nature; plant damage was mostly reported as abnormal leaf discolouration or visible injury. Drift from neighbouring application sites was most frequently reported. As of 5 October 2015, the United States Environmental Protection Agency (USEPA) had received five fluroxypyr environment incident reports. In all cases, plants were damaged, usually after having been treated directly with a product containing fluroxypyr.

9.0 Organization for Economic Co-operation and Development Status of Fluroxypyr

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups member countries and provides a forum in which governments can work together to share experiences and seek solutions to common issues.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member country to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Fluroxypyr is currently acceptable for use in other OECD member countries, including the European Union, United States, and Australia. As of 30 March 2017, no decision by an OECD member country to prohibit all uses of fluroxypyr for health or environmental reasons has been identified.

10.0 Proposed Regulatory Decision

The PMRA has determined that products containing fluroxypyr for sale and use in Canada are acceptable for continued registration with the implementation of the proposed label amendments (Appendix III).

List of Abbreviations

ADI	Acceptable daily intake
a.e.	Acid equivalent
a.i.	Active ingredient
ARfD	Acute reference dose
bw	Body weight
°C	Degree(s) celcius
cm	Centimeter(s)
EC_{50}	Effective concentration, 50% of test subjects
EEC	Expected environmental concentration
ha	Hectare
kg	Kilogram(s)
K_{oc}	Soil organic carbon-water partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	Litre(s)
LC_{50}	Lethal concentration, 50% of test subjects
LOAEL	Lowest Observed Adverse Effect Level
mg	Milligram(s)
mm Hg	Millimeter of mercury
MOE	Margin of exposure
mPa	Millipascal(s)
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Agreement
NOAEL	No Observed Adverse Effect Level
OECD	Organization for Economic Co-operation and Development
pH	-log10 hydrogen ion concentration
PMRA	Pest Management Regulatory Agency
ppm	Parts per million
PRVD	Proposed Re-evaluation Decision
REI	Restricted-entry interval
RQ	Risk quotient
µg	Microgram(s)
λ	Wavelength

Appendix I Registered Fluroxypyr Products as of 9 August 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee
24815	Commercial	Dow AgroSciences Inc.	STARANE HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
24834	Commercial	Dow AgroSciences Inc.	ATTAIN A HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
25465	Commercial	Dow AgroSciences Inc.	PRESTIGE A	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
27246	Commercial	Dow AgroSciences Inc.	TROPHY A EMULSIFIABLE CONCENTRATE HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
28537	Commercial	Dow AgroSciences Inc.	BASELINE B HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
29286	Commercial	Dow AgroSciences Inc.	GF-184 HERBICIDE	Suspension	Florasulam - 2.5 g/L Fluroxypyr - 100 g a.e./L
29450	Commercial	Syngenta Canada Inc.	PULSAR HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 113.3 g a.e./L Dicamba - 86.9 g/L
29462	Commercial	Dow AgroSciences Inc.	PRESTIGE XC A HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
29463	Commercial	Dow AgroSciences Inc.	STARANE II HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
29557	Commercial	Dow AgroSciences Inc.	RETAIN B HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
29586	Commercial	E.I. Du Pont Canada Company	PERIMETER HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
29670	Commercial	Dow AgroSciences Inc.	STARANE GBX HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
29730	Commercial	Dow AgroSciences Inc.	PERIMETER MEGA PRECISIONPAC HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
29761	Commercial	Dow AgroSciences Inc.	NUFARM TROPHY 600 A HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee
29953	Commercial	Dow AgroSciences Inc.	STELLAR A HERBICIDE	Suspension	Florasulam - 2.5 g/L Fluroxypyr - 100 g a.e./L
29958	Commercial	Dow AgroSciences Inc.	GBX HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
29965	Commercial	Dow AgroSciences Inc.	TANDEM B HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
29973	Commercial	Dow AgroSciences Inc.	ATTAIN XC A HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
30028	Commercial	Nufarm Agriculture Inc.	NUFARM FLUROXYPYR 180 HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
30077	Commercial	Dow AgroSciences Inc.	OCTTAIN XL HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 90 g a.e./L (2,4-Dichlorophenoxy)acetic acid - 360 g/L
30094	Commercial	E.I. Du Pont Canada Company	PERIMETER II HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
30095	Commercial	Dow AgroSciences Inc.	PERIMETER MEGA XC PRECISIONPAC HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
30194	Commercial	Nufarm Agriculture	NUFARM FLUROXYPYR HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
30389	Commercial	Arysta Lifescience North America	FLUROXYPYR EC HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 348 g a.e./L
30391	Commercial	Syngenta Canada	AXIAL XTREME HERBICIDE	Emulsifable Concentrate	Pinoxaden - 50 g/L Fluroxypyr - 87.5 g a.e./L
30456	Commercial	Loveland Products Canada	MOMENTUM	Emulsifable Concentrate	Fluroxypyr - 90.0 g a.e./L Clopyralid - 90.0 g/L
30580	Commercial	Arysta Lifescience North America	ARY 0548-019 HERBICIDE	Suspension	Flucarbazone - 36.3 g/L Fluroxypyr - 200 g a.e./L
30667	Commercial	Arysta Lifescience North America	FLUROXYPYR WDG HERBICIDE	Wettable Granules	Fluroxypyr - 27.8%
30690	Commercial	Nufarm Agriculture Inc.	ENFORCER D HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 80 g a.e./L (2,4-Dichlorophenoxy)acetic acid - 240 g/L Bromoxynil - 190 g/L
30691	Commercial	Nufarm Agriculture Inc.	ENFORCER M HERBICIDE	Emulsifable Concentrate	(2-methyl-4-chlorophenoxy)acetic acid - 200 g/L Fluroxypyr - 80 g a.e./L Bromoxynil - 200 g/L

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee
30795	Commercial	Dow AgroSciences Inc.	SIGHTLINE B HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
30815	Commercial	Adama Agriculture Solutions Canada, LTD.	FLUROXYPYR 180 EC	Emulsifable Concentrate	Fluroxypyr - 150 g a.e./L
31303	Commercial	Dow AgroSciences Inc.	PIXXARO A HERBICIDE	Emulsifable Concentrate	Halauxifen - 16.25 g/L Fluroxypyr - 250 g a.e./L
31428	Commercial	Dow AgroSciences Inc.	PRESTIGE XL HERBICIDE	Emulsifable Concentrate	(2-methyl-4-chlorophenoxy)acetic acid - 239.5 g/L Fluroxypyr - 61.56 g a.e./L Clopyralid - 42.72 g/L
31434	Commercial	Nufarm Agriculture Inc.	SIGNAL F HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 217 g a.e./L; CFP-112 g/L;
31626	Commercial	Dow AgroSciences Inc..	SCUTTLE HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 90 g a.e./L (2,4-Dichlorophenoxy)acetic acid - 360 g/L
31646	Commercial	Adama Agriculture Solutions Canada, LTD.	OUTSHINE	Suspension	Florasulam - 2.5 g/L Fluroxypyr - 100 g a.e./L
31673	Commercial	Syngenta Canada Inc.	TRAXOS® TWO BROADLEAF COMPONENT	Emulsifable Concentrate	Fluroxypyr - 90 g a.e./L (2,4-Dichlorophenoxy)acetic acid - 360 g/L
31685	Commercial	E.I. Du Pont Canada Company	DUPONT TRAVALLAS HERBICIDE	Suspension	Thifensulfuron-methyl - 30 g/L Metsulfuron-methyl - 3.0 g/L Fluroxypyr - 150 g a.e./L
31727	Commercial	Loveland Products Canada, Inc.	HAT TRICK HERBICIDE	Emulsifable Concentrate	(2-methyl-4-chlorophenoxy)acetic acid - 224 g/L Fluroxypyr - 61 g a.e./L Clopyralid - 61 g/L
32006	Commercial	Bayer Crop Science Inc.	FX HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 180 g a.e./L
32099	Commercial	Dow AgroSciences Inc.	STELLAR XL HERBICIDE	Emulsifable Concentrate	(2-methyl-4-chlorophenoxy)acetic acid - 350 g/L Florasulam - 2.5 g/L Fluroxypyr - 100 g a.e./L
32143	Commercial	E.I. Du Pont Canada Company	DUPONT SENTRALLAS HERBICIDE	Suspension	Thifensulfuron-methyl - 30 g/L Fluroxypyr - 150 g a.e./L
32359	Commercial	Dow AgroSciences Inc.	IMPEDE HERBICIDE	Emulsifable Concentrate	Fluroxypyr - 90 g a.e./L Clopyralid - 90 g/L

Registration Number	Marketing Class	Registrant	Product Name	Formulation	Guarantee
32565	Commercial	Dow AgroSciences Inc.	STARANE DRY HERBICIDE	Wettable Granules	Fluroxypyr - 35%
29350	Manufacturing	Dow AgroSciences Inc.	STARANE MANUFACTURING CONCENTRATE	Solid	Fluroxypyr - 68%
30193	Manufacturing	Nufarm Agriculture Inc.	NUFARM FLUROXYPYR MANUFACTURING CONCENTRATE	Solid	Fluroxypyr - 68%
31202	Manufacturing	Dow AgroSciences Inc.	GF-1203 MANUFACTURING CONCENTRATE	Emulsifable Concentrate	Fluroxypyr - 90 g a.e./L Clopyralid - 90 g/L
31933	Manufacturing	E.I. Du Pont Canada Company	DUPONT TRAVALLAS MUP	Suspension	Thifensulfuron-methyl - 30 g/L Metsulfuron-methyl - 3.0 g/L Fluroxypyr - 150 g a.e./L
31991	Manufacturing	Dow AgroSciences Inc.	GF-1784 MANUFACTURING CONCENTRATE	Emulsifable Concentrate	Fluroxypyr - 333 g a.e./L
32144	Manufacturing	E.I. Du Pont Canada Company	DUPONT SENTRALLAS MUP	Suspension	Thifensulfuron-methyl - 30 g/L Fluroxypyr - 150 g a.e./L
24814	Technical	Dow AgroSciences Inc.	STARANE F TECHNICAL HERBICIDE	Solid	Fluroxypyr - 68%
30335	Technical	Agrogill Chemicals PTY LTD.	FLUROXYPYR AGROGILL TECHNICAL GRADE ACTIVE INGREDIENT	Solid	Fluroxypyr - 68%
30507	Technical	Adama Agriculture Solutions Canada, LTD.	MANA FLUROXYPYR TECHNICAL	Solid	Fluroxypyr - 68.0%
30955*	Technical	Nufarm Agriculture Inc.	NUFARM FLUROXYPYR-MEPTYL TECHNICAL	Solid	Fluroxypyr - 68%

* IMEP (import for manufacture of exported product): To be used only in the manufacture (formulating, repackaging, repouring) of a pest control product solely for export from Canada. Not subject to re-evaluation.

Appendix II Toxicology Endpoints for Health Risk Assessment for Fluroxypyr

Exposure Scenario	Study	Point of Departure and Endpoint	CAF or Target MOE[1]
Acute dietary general population	-	No relevant acute toxicity endpoint was identified	-
	ARfD = N/A		
Chronic dietary	2-year rat chronic toxicity/oncogenicity	NOAEL = 100 mg/kg bw/day LOAEL = 500 mg/kg bw/day Affect observed = kidney nephrosis	100
	ADI[2] = 1 mg/kg bw/day		
Short and Intermediate term dermal	21-day dermal study in rabbits[3]	NOAEL = 1000 mg/kg bw/day Absence of adverse effects at the highest dose tested	100
Short and Intermediate term inhalation	2-year rat chronic toxicity/oncogenicity[4]	NOAEL = 100 mg/kg bw/day Affect observed = kidney nephrosis	100
Cancer	No evidence of carcinogenicity		

1. CAF (composite assessment factor) refers to the total uncertainty and *Pest Control Products Act* factor for dietary assessments. MOE refers to a target MOE for occupational assessments and is the total uncertainty and *Pest Control Products Act* factor. Standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were applied for both the CAF and the MOE. In addition, the *Pest Control Products Act* factor was set at 1-fold.
2. The ADI is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{CAF}} = \frac{(100 \text{ mg/kg bw/day})}{(10 \times 10 \times 1)} = 1 \text{ mg/kg bw/day of fluroxypyr}$$

3. Since a dermal NOAEL was selected, a route-to-route dermal absorption extrapolation factor was not required.
4. Since an oral NOAEL was selected, an inhalation absorption factor of 100% (default value) was used in route-to-route extrapolation.

Appendix III Label Amendments for End-Use Products Containing Fluroxypyr

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements, and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) Under **PRECAUTIONS**, the following statements must be included:

"Do not enter or allow workers entry into treated areas during the restricted-entry interval (REI) of 12 hours."

"DO not use in residential areas. Residential areas are defined as any use site where bystanders, including children, could be exposed during or after application. This includes homes, schools, parks, playgrounds, playing fields, public buildings, or any other area where the general public, including children, could be exposed."

"Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings."

II) The following statements must be included in a section entitled **ENVIRONMENTAL PRECAUTIONS:**

"TOXIC to non-target terrestrial plants and aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE."

"To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay."

"Avoid application when heavy rain is forecast."

"Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

III) For products containing aromatic petroleum distillates, the following statement must be included in a section entitled **ENVIRONMENTAL PRECAUTIONS**:

"This product contains (an) active ingredient(s) and aromatic petroleum distillate(s) which are toxic to aquatic organisms."

IV) In a section entitled **STORAGE,** the following must be removed**:**

"Do not contaminate food, feedstuffs or domestic water supplies."

V) The following statement must be included in a section entitled **STORAGE**:

"To prevent contamination, store this product away from food or feed."

VI) The following statements must be included in a section entitled **DIRECTIONS FOR USE:**

"As this product is not registered for the control of pests in aquatic systems, **DO NOT** use to control aquatic pests."

"**DO NOT** contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

VII) The following **buffer zone statements** must be included on the label:

Buffer Zone Related Label Statements Required for End-Use Product ARY 0548-019 Herbicide (PCP# 30580):

Add to DIRECTIONS FOR USE:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

DO NOT apply by air.

Buffer zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Spring wheat (including durum wheat)	1	0	1	1	3

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Drift Mitigation page, found on the Pesticides and Pest Management portion of the Canada.ca website.

Buffer Zone Related Label Statements Required for Fluroxypyr End-Use Products Requiring Applications with Spray Droplets of ASAE Coarse Classification (except for PCP# 30580):

Add to DIRECTIONS FOR USE:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) coarse classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Spring wheat, durum wheat, winter wheat, spring barley, oats, seedling and established fescue and forage grasses for seed, canary seed, foxtail millet		1	0	1	1	1
Aerial	Wheat, barley, oats, canary seed	Fixed wing	4	0	1	1	70
		Rotary wing	1	0	1	1	55

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Drift Mitigation page, found on the Pesticides and Pest Management portion of the Canada.ca website.

Buffer Zone Related Label Statements Required for Fluroxypyr End-Use Products Requiring Applications with Spray Droplets of ASAE Medium Classification:

Add to DIRECTIONS FOR USE:

Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. Boom height must be 60 cm or less above the crop or ground.

Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 16 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) medium classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan.

Buffer zones:

Spot treatments using hand-held equipment **DO NOT** require a buffer zone.

For application to rights-of-way, buffer zones for protection of sensitive terrestrial habitats are not required; however, the best available application strategies which minimize off-site drift, including meteorological conditions (for example, wind direction, low wind speed) and spray equipment (for example, coarse droplet sizes, minimizing height above canopy), should be used. Applicators must, however, observe the specified buffer zones for protection of sensitive aquatic habitats.

The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands), sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	Crop	Buffer Zones (metres) Required for the Protection of:				
		Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
		Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
Field sprayer	Spring wheat, durum wheat, winter wheat, spring barley, oats, seedling and established fescue and forage grasses for seed, canary seed, foxtail millet, new and established grass pastures	1	0	1	1	3

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:				
			Freshwater Habitat of Depths:		Estuarine/Marine Habitats of Depths:		Terrestrial habitat
			Less than 1 m	Greater than 1 m	Less than 1 m	Greater than 1 m	
	Permanent pasture, rangeland, industrial areas, other non-crop areas		1	1	1	1	5*
Aerial	Wheat, barley, oats	Fixed wing	5	0	1	1	95
		Rotary wing	3	0	1	1	80

* Buffer zones for the protection of terrestrial habitats are not required for use on rights-of-way including railroad ballast, rail and hydro rights-of-way, utility easements, roads, and training grounds and firing ranges on military bases.

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Drift Mitigation page, found on the Pesticides and Pest Management portion of the Canada.ca website.

References

I) Information Considered in the Re-evaluation not Submitted by the Registrants

Published Studies

PMRA Document Number	Reference
2206864	PRD2012-18. Proposed Registration Decision: Fluroxypyr

II) Information Considered in the Re-evaluation Submitted by the Registrants

Published Studies

PMRA Document Number	Reference
2119706	Tolerance of foxtail millet to combinations of bromoxynil, clopyralid, fluroxypyr, and MCPA. Authored by May et al., and published on the journal of Weed Technology, 2009 (23) 94-98. DACO 10.3.2.

Unpublished Studies

PMRA Document Number	Reference
2259498	1996, Fluroxypyr 1-methylheptyl ester: the toxicity to *Skeletonema costatum*, DACO: 9.8.3
2259497	1996, Fluroxypyr 1-methylheptyl ester: acute toxicity to the sheepshead minnow, *Cyprinodon variegatus*, DACO: 9.5.2.4
2259496	1994, Fluroxypyr: acute toxicity to the silverside, *Menidia beryllina*, DACO: 9.5.2.4
2076326	2011, Starane II Field Trial Reports, DACO: 10.2.3.3,10.3.2
2078921	2011, Value Summaries - Starane II, Sub no. 2011-2831, aerial application, DACO: 10.1
2034332	2000, BAS 652 04 H - Acute oral toxicity in rats. Report EU-10A0475/991139,Experimental Toxicology and Ecology, BASF AG. DACO: 4.6.1
2034333	2000. BAS 652 04 H - Acute dermal toxicity study in rats. Report EU-11A0475/991138, Experimental Toxicology and Ecology, BASF AG. DACO: 4.6.2
2034334	2000. BAS 652 04 H - Acute inhalation toxicity study in Wistar rats, 4-hour liquid aerosol exposure. Report EU-13I0475/997015, Experimental Toxicology andEcology, BASF AG. EU-13I0475/997015. DACO: 4.6.3

PMRA Document Number	Reference
2034335	2000. Amednment No. 1, BAS 65204 H - Acute eye irritation in rabbits. Project No.: 11H0475/992265, Experimental Toxicology and Ecology, BASF AG. DACO: 4.6.4
2034336	2000. BAS 652 04 H - Acute eye irritation in rabbits. Report EU- 11H0475/992265, Experimental Toxicology and Ecology, BASF AG. DACO: 4.6.4
2034337	2000. BAS 652 04 H - Acute Dermal Irritation/Corrosion in Rabbits. Report EU-18H0475/992263, Experimental Toxicology and Ecology, BASF AG. DACO:4.6.5
2034338	2000. BAS 652 04 H - BUEHLER Test in Guinea Pigs. Report EU-32H0475/992264, Experimental Toxicology and Ecology, BASF AG. DACO: 4.6.6
2288904	2012, LP6425 Field Trial Reports, DACO: 10.2.3.3.
2288880	2013, Product ID, LP6425 Herbicide, DACO: 3.1 CBI
2288881	2013, Formulation Process and Specificiations, GF-1681, DACO: 3.2.1,3.2.2,3.3.1 CBI
2288882	2006, Extension of Analytical Method EU-AM-97-005 for the Analysis of Fluroxypyr Meptyl, Clopyralid, and MCPA 2-Ethylhexyl Ester in Formulation GF-1681, DACO: 3.4.1 CBI
2288883	1997, Analytical Method for the analysis of Ariane Herbicide, DACO: 3.4.1 CBI
2288885	2013, Summary - Chemical and Physical Properties, DACO: 3.5 CBI
2288886	2006, Storage Stability and Package Corrosion Characteristics of GF-1681; Two Week Accelerated Study, DACO: 3.5 CBI
2288888	2006, Determination of Explosive Properties and Auto-Ignition Temperature for GF-1681, DACO: 3.5 CBI
2288889	2006, Oxidising properties of GF-1681, DACO: 3.5 CBI
2302225	2013, Physical and Chemical Properties, DACO: 3.5
2361663	2006, Product Chemistry Data for Colt + Sword, DACO: 3.0 CBI
2361664	2013, Description of the formulation process, DACO: 3.2.2 CBI
2361665	2013, Discussion of the formation of impurities of toxiclogical concern, DACO:3.2.3 CBI
2420669	2014, Storage Stability and Corrosion Characteristics, DACO: 3.5.10,3.5.14 CBI
1672801	2000, Magnitude of Residue of Fluroxypyr in Range and Pasture Grasses, DACO: 7.4.1
2119704	Prestige Herbicide Tank-mix (fluroxypyr + clopyralid + MCPA) for the control of broadleaf weeds and Canada thistle in foxtail millet for animal feed. DACO 10.3.2. pp. 5.
1920755	GF-184 Herbicide Pasture Biological Assessment Dossier, DACO 10.1

PMRA Document Number	Reference
1960266	Additional information-Grass pasture, DACO 10.6
2046204	Composition Comparison of GF-184 and EF-1466, DACO 3.0
1672773	2000, Metabolism of Fluroxypyr in Onions (Rijnsburger Hyton), DACO: 6.3
1672776	1996, Determination of Residues of Fluroxypyr in Wheat Processed Fractions Amended Report, DACO: 7.2.1
1672778	1991, Determination of Residues of Fluroxypyr in Processed Fractions of Wheat, DACO: 7.2.1
1672779	1996, Validation Report for the Determination of Residues of Fluroxypyr and Fluroxypyr 1-Methylheptyl Ester as the Acid Equivalent in the Grain, Forage, Straw, and Hay of Wheat, Barley, and Oats by Capillary Gas Chromatography with mass Selective Detection, DACO: 7.2.1,7.2.2
1672780	2000, Residues of Fluroxypyr and Fluroxypyr 1-Methylheptyl Ester as the Acid Equivalent in Grass Forage and Hay by Capillary Gas Chromatography with Mass Selective Detection, DACO: 7.2.1,7.2.2
1672782	1991, Determination of Residues of Fluroxypyr in Corn Forage, Grain and Fodder by Gas Chromatography/Mass Spectrometry, DACO: 7.2.1,7.2.2
1672783	2000, Determination of Residues of Fluroxypyr and Fluroxypyr 1-Methylheptyl Ester as the Acid Equivalent in Sorghum Grain, Forage, and Stover by Capillary Gas Chromatography with Mass Selective Detection, DACO: 7.2.1,7.2.2
1672785	1996, Independent Laboratory Validation of Method GRM 96.02- Determination of Residues of Fluroxypyr and Fluroxypyr 1-Methylheptyl Ester as the Acid Equivalent in the Grain, Forage, Straw and Hay of Wheat, Barley and Oats by Capillary Gas Chromatography with Mass Selective Detection, DACO: 7.2.3
1672791	1990, Determination of Residues of Fluroxypyr in Wheat, Barley and Oat Grain and Straw, DACO: 7.4.1
1672792	1990, Determination of Residues of Fluroxypyr in Wheat, Barley and Oat Grain and Straw, DACO: 7.4.1
1672793	1996, The Magnitude of Residue of Fluroxypyr in Wheat Following Postemergence Application of XRM-5316 Amended Report, DACO: 7.4.1
1672794	1996, The Magnitude of Residue of Fluroxypyr in Oats Following Postemergence Application of XRM-5316 Amended Report, DACO: 7.4.1
1672795	1996, The Magnitude of Residue of Fluroxypyr in Barley Following Postemergence Application of XRM-5316 Amended Report, DACO: 7.4.1
1672796	2007, Residues of Fluroxypyr in Sweet Corn, DACO: 7.4.1
1672797	2007, Residues of Fluroxypyr in Sweet Corn, DACO: 7.4.1

PMRA Document Number	Reference
1672798	2000, Magnitude of Residue of Fluroxypyr in Sorghum Forage, Grain and Fodder After Use of Fluroxypyr Methylheptyl Ester Herbicide, DACO: 7.4.1,7.4.6
1672802	2006, Fluroxypyr: Magnitude of the Residue on Pear, DACO: 7.4.1
1672803	2003, Fluroxypyr: Magnitude of the Residue on Onion (Dry Bulb), DACO: 7.4.1
1672804	2006, Fluroxypyr: Magnitude of the Residue on Apple, DACO: 7.4.1
1672806	1981, Determination of Residues of Fluroxypyr in Wheat Grain and Straw- A Bridging Study, DACO: 7.4.1
1672807	1981, Determination of Residues of Fluroxypyr in Wheat Grain and Straw- A Bridging Study, DACO: 7.4.1
1672808	1999, Determination of Residues of Fluroxypyr in Sweet Corn Ears, Forage, and Processed Fractions, DACO: 7.4.1,7.4.5,7.4.6
1672809	1999, Magnitude of the Residue of Fluroxypyr in Field Corn and Corn Processed Products, DACO: 7.4.1,7.4.5
1166924	Frozen Storage Stability of Fluroxypyr in Winter Wheat Immature Plant, Grain and Straw. (GHE-P-4830;ST94-17;B2A;CEMS-311;CEMR-311;ST94-017).(STARANE F HERBICIDE), DACO: 7.3
2418223	2014, AQUATIC VASCULAR PLANTS, DACO 9.8.5
2648532	2013, Fluroxypyr-meptyl- Growth Inhibition of *Myriophyllim spicatum* in a Water/Sediment System, DACO 9.8.5
2418241	2014, AQUATIC VASCULAR PLANTS, DACO 9.8.5
2648536	2012, Fluroxypyrl- Growth Inhibition of *Myriophyllim spicatum* in a Water/Sediment System, DACO 9.8.5
1359526	Chemical and Physical Properties of Technical Pesticide Material, DACO: 2.14.1,2.14.11,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.8,2.14.9
1359598	1984, Report of the Odour and Taint Potential of Fluroxypyr Acid and 1-methyl heptyl Ester and Haloxyfop Acid and Ethoxy Ethyl Ester, DACO: 2.14.3
1359594	Technical Chemistry file FLR-DOW-1, DACO: 2.99
1889185	2010, Fluroxypyr Meptyl Physical Chemical tests, DACO: 2.14.1,2.14.10, 2.14.11, 2.14.12,2.14.13,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9 CBI
1967929	2007, Validation of Anaytical Method M616 for Technical Fluroxypyr Meptyl, DACO: 2.14.12 CBI
1969080	2009, Physical State, Colour and Odour of Fluroxypyr Meptyl Technical, DACO: 2.14.1,2.14.2,2.14.
1969091	Anonymous, 1999, EC-Review report for the active substance fluroxypyr, DACO: 2.14.10,2.14.11,2.14.4,2.14.5,2.14.7,2.14.8,2.14.9

PMRA Document Number	Reference
1969086	2009, Relative Density of Fluroxypyr Meptyl Technical, DACO: 2.14.6
1969089	2009, Solubility of Fluroxypyr Meptyl in Organic Solvents, DACO: 2.14.8
1969082	2009, Partition Coefficient of Fluroxypyr Meptyl tech. (CBI Removed), DACO: 2.14.11
1969084	2009, UV/VIS Absorption Spectrum of Fluroxypyr Meptyl tech, DACO: 2.14.12
1809391	DACO: 2.0_DOC
1658169	2008, FOR-08-37 Starane F Fluroxypyr [CBI Removed], DACO: 2.0 CBI
1836483	2009, Cover Letter, Starane F response, 2008-4564, DACO: 0.8
1868576	2010, Detailed response, Starane F Technical Herbicide, Reg. 24814, Clarification response for 2008-4564, DACO: 2.11.3,2.13.1 CBI
1868579	2009, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of Formulation [CBI Removed], Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Starane F, DACO: 2.13.3 CBI
841463	DACO: 2_0
1889161	DACO 2.11.2 Description of starting materials , DACO: 2.11.2 CBI
1889173	2.11.3 Detailed Production Process , DACO: 2.11.3 CBI
1979337	DACO 2.11.3 Revised Production Process STEP D.pdf, DACO: 2.11.3 CBI
1969063	2008, Fluroxypyr-meptyl Manufacturing Process, DACO: 2.11.1,2.11.3,2.11.4 CBI
1969070	2010, Chemistry-2.11.2-Fluroxypyr TGAI-Starting Materials, DACO: 2.11.2 CBI
1969065	2010, Discussion on [CBI Removed] DACO: 2.11.4 CBI
1969068	2010, Fluroxypyr Meptyl Tech Consideration [CBI Removed]
2036307	2011, Spec for [CBI Removed], DACO: 2.11.2 CBI
2036309	2011, Spec-[CBI Removed], DACO: 2.11.2 CBI
2036310	2011, Spec-[CBI Removed], DACO: 2.11.2 CBI
2036311	2011, [CBI Removed] production, DACO: 2.11.2 CBI
2036312	2011, [CBI Removed], DACO: 2.11.2 CBI
2036313	2011, [CBI Removed], DACO: 0.9.2
2036314	2011[CBI Removed] production, DACO: 0.9.2
2036315	2011, Spec-[CBI Removed], DACO: 0.9.2
2036316	2011, Spec-[CBI Removed] source, DACO: 0.9.2
2036318	2011, Spec-[CBI Removed] source, DACO: 0.9.2

PMRA Document Number	Reference
1359731	5 Batch Characterization of Starane F Herbicide, [CBI Removed]@ in Part 2 Chemistry dated 1996/05/07, [CBI Removed], vol. # 36, page 5
1359733	Confirmation of Identity and Quantitation of [CBI Removed] in Starane F Herbicide, [CBI Removed] in Part 2 Chemistry dated 1996/05/07, [CBI Removed], vol. # 36, page 7
1658166	2006, 5 Batch Report FOR-05-061 Starane F [CBI Removed], DACO 2.0 CBI
1658167	2008, 5 Batch Report FOR-08-37 Starane F [CBI Removed] DACO: 2.0 CBI
1658169	2008, FOR-08-37 Starane F Fluroxypyr [CBI Removed], DACO: 2.0 CBI
1868579	2009, Group A-Product Identity and Composition, Description of Materials Used to Produce the Product, Description of Production Process, Discussion of [CBI Removed], Preliminary Analysis, Certified Limits, and Enforcement Analytical Method for Starane F, DACO: 2.13.3 CBI
1889184	2009, Analysis of 5 Batches of Technical Fluroxypyr Meptyl, DACO: 2.13.3 CBI
1967928	Manufacturing dates for the 5Batches used in the Batch analysis, DACO: 2.13.3
1969072	2008, Fluroxypyr Technical 5-Lots Analysis and Method Validation, DACO: 2.13.1,2.13.2,2.13.3 CBI
1969074	2008, Fluroxypyr Technical 5-Lots Analysis and Method Validation, DACO: 2.13.1,2.13.2,2.13.3 CBI
1969076	2008, Date of production of batches [CBI Removed], DACO: 2.13.3 CBI
1969078	2009, Date of production of batches [CBI Removed], DACO: 2.13.3 CBI
1359741	Technical Chemistry File FLR-[CBI Removed], DACO: 2.99
1359594	Technical Chemistry file FLR-[CBI Removed], DACO: 2.99
1359542	1986, Letter from [CBI Removed] re: Starane Herbicidal Products/[CBI Removed], DACO: 2.13.
2680118	2016, Scientific Rationale - Starane F Technical - Fluroxypyr Re-eval 14-5438, DACO: 2.13.4 CBI
2634790	2016, [CBI Removed], DACO: 2.13.4 CBI
2765289	DACO: 2.13.4 CBI
2765290	DACO: 2.13.4 CBI
1889174	2.11.4 Discussion [CBI Removed], DACO: 2.11.4 CBI
1969065	2010, Discussion [CBI Removed]., DACO: 2.11.4 CBI
1969068	2010, Fluroxypyr Meptyl Tech Consideration [CBI Removed], DACO: 2.11.4 CBI
2634790	2016, [CBI Removed], DACO: 2.13.4 CBI

PMRA Document Number	Reference
2774747	DACO: Data_Call-in_Letter_to_Registrant_Sec19(1)_Notice_Signed
2778823	Data analysis